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## NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 02/11/2002

ANN M MUETING  
MEUTING RAASCH & GEBHARDT  
P O BOX 581415  
MINNEAPOLIS, MN 55458

EXAMINER

SOUAYA, JEHANNE E

ART UNIT

CLASS-SUBCLASS

1634

435-006000

DATE MAILED: 02/11/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/181,585	10/28/1998	LAURA P.W. RANUM	110.00900101	1075

TITLE OF INVENTION: SPINOCEREBELLAR ATAXIA TYPE 8 AND METHODS OF DETECTION

TOTAL CLAIMS	APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
23	nonprovisional	NO	\$1280	\$0	\$1280	05/13/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

## HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

Complete and mail this form, together with applicable fee(s), to:

**Box ISSUE FEE**  
**Assistant Commissioner for Patents**  
**Washington, D.C. 20231**

**MAILING INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

7590 02/11/2002

ANN M MUETING  
MEUTING RAASCH & GEBHARDT  
P O BOX 581415  
MINNEAPOLIS, MN 55458

Note: The certificate of mailing below can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

**Certificate of Mailing**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

	(Depositor's name)
	(Signature)
	(Date)

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23	nonprovisional	NO	\$1280	\$0	\$1280	05/13/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
SOUAYA, JEHANNE E	1634	435-006000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

"Fee Address" indication (or "Fee Address" Indication form PTO/SB/47) attached.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1. \_\_\_\_\_  
2. \_\_\_\_\_  
3. \_\_\_\_\_

**3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent)  individual  corporation or other private group entity  government

4a. The following fee(s) are enclosed:

Issue Fee  
 Publication Fee  
 Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

A check in the amount of the fee(s) is enclosed.  
 Payment by credit card. Form PTO-2038 is attached.  
 The Commissioner is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, United States Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington, D.C. 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMIT THIS FORM WITH FEE(S)**



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7590	02/11/2002		EXAMINER	
ANN M MUETING MEUTING RAASCH & GEBHARDT P O BOX 581415 MINNEAPOLIS, MN 55458			SOUAYA, JEHANNE E	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 02/11/2002				

**Determination of Patent Term Extension under 35 U.S.C. 154 (b)**  
(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

**Notice of Allowability**

Application No. <b>09/181,585</b>	Applicant(s) <b>Ranum et al</b>
Examiner <b>Jehanne Souaya</b>	Art Unit <b>1634</b> <b>1655</b>

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to the after final amendment of 01/23/2001.
2.  The allowed claim(s) is/are 2-4, 8, 10, 13, 15-19, 37, 40, 43-49, and 52.
3.  The drawings filed on \_\_\_\_\_ are acceptable as formal drawings.
4.  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a)  All      b)  Some\*      c)  None      of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

5.  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

6.  Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7.  Applicant MUST submit NEW FORMAL DRAWINGS
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
  - (c)  including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8.  Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

**Attachment(s)**

1 <input type="checkbox"/> Notice of References Cited (PTO-892)	2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3 <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.
5 <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449), Paper No(s). _____	6 <input type="checkbox"/> Examiner's Amendment/Comment
7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance
9 <input type="checkbox"/> Other	

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## REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: the claims are drawn to a method of detecting the presence of a DNA fragment located within an at risk allele of an SCA8 (spinocerebellar ataxia type 8) coding sequence by analyzing an amplified DNA fragment, amplified using primers chosen from nucleotides 1-448 or 726-1,159 of SEQ ID NO:1, having at least about 80 CTG repeats in the repeat region or at least 92 combined CTA and CTG repeats in the repeat region. The claims are allowable over the prior art as the prior art does not teach or fairly suggest an at risk allele of SCA8 or the sequence of SEQ ID NO:1 or primers chosen from nucleotides 1-448 or 726-1,159 of SEQ ID NO:1. The claims are further drawn to the above method using primers with SEQ ID NOS 4-6, 8-9 and 12. These claims are allowable over the prior art as the art does not teach oligonucleotides consisting of these sequences. The claims are also drawn to determining whether an individual is at risk or not at risk for developing SCA8 by detecting the number of repeats in the repeat region of SCA8 wherein an individual who has least about 80 CTG repeats in the repeat region or at least 92 combined CTA and CTG repeats in the repeat region is at risk while an individual that has less than 80 CTG repeats or no greater than about 91 combined CTA and CTG repeats is not at risk of developing SCA8. These claims are allowable over the prior art as the art does not teach or fairly suggest determining whether an is or is not at risk for developing SCA8 nor does the art teach a SCA8 coding sequence or how many CTG or combined CTA and CTG repeats in an individual's SCA8 coding sequence are

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indicative of developing SCA8. The kits and oligonucleotides of the instantly claimed invention, which are drawn to oligonucleotides chosen from nucleotides 1-448 or 726-1,159 of SEQ ID NO:1 or to oligonucleotides which consist of at least 15 contiguous nucleotides from nucleotides 1-448 or 726-1,159 of SEQ ID NO:1, are allowable over the prior art does not teach the sequence of SEQ ID NO 1 or to oligonucleotides which are chosen from or consist of at least 15 contiguous nucleotides of nucleotides 1-448 or 726-1,159 of SEQ ID NO:1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya  
Patent examiner

Art Unit 1634

*Jehanne Souaya*  
Feb. 7, 2002

*W. Gary Jones*  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

## INFORMATION ON HOW TO EFFECT DRAWING CHANGES

### 1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

### 2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.